

REMARKS

Claims 6, 7, 20, 24 and 27 are active. New Claims 30-32 have been added. Claim 24 is directed to the elected species where component (B) is zingerol and has been indicated as being allowable. Independent Claim 6 has been revised to provide an objective standard for the hotness of the heat component based on the heat components exemplified on page 8 of the specification. Claim 6 now employs the transitional claim language “consisting essentially of”. Claims 30-32 have been added and track the originally elected species. Accordingly, the Applicants do not believe that any new matter has been added. Favorable consideration and allowance of this application is now respectfully requested.

The Applicants thank Examiner Coe for the courteous and helpful discussion on April 18, 2006. Ways to related the hotness of the required heat components to compounds disclosed in the specification were discussed as a potential means to address the indefiniteness rejection. Use of the transitional phrase “consisting essentially of” was discussed.

Election/Restriction

The Applicants previously elected Group II (method of treatment) and the a species of compound for use in the elected method comprising (A) chlorogenic acid and (B) a central nervous system stimulating component. The Restriction Requirement has been made FINAL.

On June 2, 2005 the Applicants were required to further elect a single species of component (B) and subsequently elected (B) zingerol which is a heat component of ginger (*Zingiberaceae*). The claims as directed to the elected species (A) chlorogenic acid + (B) zingerol have been found in condition for allowance except for formal matters. Since zingerol falls within the subgenus of isolated heat component of *Zingiberaceae* described in

Claim 6, the Applicants respectfully request that heat components related to zingerol from this subgenus be examined.

Rejection—35 U.S.C. § 112, second paragraph

Claims 6, 7, and 20 were rejected under 35 U.S.C. 112, second paragraph, as indefinite for employing the term “heat component”. This rejection is moot in view of the amendments above which define the degree of hotness of the heat components by reference to heat components exemplified in the specification. As discussed in their last response, the Scoville scale is a conventional way to compare the hotness of foods and thus whether or not a given heat component falls within the claims could easily be determined by comparison with the Scoville scale values of the exemplified heat components. Accordingly, the Applicants request that this rejection be withdrawn since one of skill in the art would understand the meaning of this term when read in light of the specification.

Rejection—35 U.S.C. § 103

Claims 6, 7, 20 and 27 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al., Chinese Pharm. Journal 46:575 and Hsia et al., U.S. Patent No. 6,440,464. The claims are now directed to compositions “consisting essentially” of isolated chlorogenic acid and capsaicin.

Cheng, Table 1 on page 579, only refers to the effects of chlorogenic acid and does not disclose or suggest combining it with capsaicin.

Hsia et al., U.S. Patent 6,440,464, discloses a complex mixture of ingredients only one of which is capsaicin. While commercially obtained capsaicin is described in col. 4, lines 53-59, there is no suggestion in Hsia for treating hypertension using capsaicin. Thus, there is no suggestion for a method of administering a composition which “consists essentially of

chlorogenic acid and capsaicin". In fact, Hsia teaches away from a method using such a composition by disclosing that the novelty of his composition lies in a complex combination of ingredients, see Hsia, col. 3, lines 33-37. Furthermore, the disclosure of Hsia is prophetic even with respect to the complex mixtures disclosed by that patent. While col. 4, lines 1-3, indicates an object of the invention is to provide compositions that will lower blood pressure, there are no examples of the claimed compositions actually reducing blood pressure. Thus, the Hsia patent merely alleges that the claimed compositions treat cardiovascular disease, but provides no evidence that they do.

Even were there some general motivation to treat hypertension by combining the products of Cheng and Hsia, these documents provide no reasonable expectation of success that administering a composition consisting essentially of chlorogenic acid and capsaicin would actually treat hypertension. Hsia does not suggest that the combination of chlorogenic acid and a heat component, such as zingerol or capsaicin, would be effective for treating hypertension. On the other hand, Example 2 of the specification shows the anti-hypertensive activity of such a combination.

Moreover, one with ordinary skill in the art would not reasonably expect that a complex mixture of ingredients of Hsia and chlorogenic acid would necessarily exhibit any effect on hypertension since the interaction of the Hsia composition with chlorogenic acid could negate or inhibit the effects observed by Cheng. Common drug interactions include pharmacodynamic (where one drug competes for the same receptor site as another) and pharmacokinetic (where the absorption, distribution, metabolism or excretion of one drug is affected by the presence of another). For example, it is commonly known that consumption of grapefruit juice inhibits the uptake or activity of many drugs (see Oesterheld, previously attached). Hsia, in fact, indicates that grapefruit juice (col. 7, lines 37-43), as well as other complex and potentially suspect juices and herbal components are integral components of his

mixture. Due to complexity of the mixture of Hsia and the possibility of drug interactions which negate the hypertensive effects of chlorogenic acid of Cheng (or alternatively, those of the Hsia composition) one with ordinary skill in the art would not have had a reasonable expectation of success in treating hypertension by merely combining the products of Cheng and Hsia.

Since neither Cheng nor Hsia suggest treating hypertension by administering a compositions consisting essentially of chlorogenic acid and capsaicin, invention, nor provide any reasonable expectation of success for using this combination to treat hypertension, the Applicants respectfully request that this rejection now be withdrawn.

Provisional Rejection—Obviousness-type Double Patenting

Claims 6, 7, 20 and 27 were rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending U.S. Applications 09/922,694, 10/826,289, 10/632,810, 10/810,611, or 11/106,428, in view of U.S. Patent No. 6,440,464. The Applicants respectfully request that these provisional rejections be held in abeyance pending the identification of otherwise allowable subject matter in the present application, see MPEP 804(I)(B).

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

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